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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,720	12/22/2005	Richard F. Allison	6550-000072/NPB	9816
27572 7590 12/03/2008 HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			EXAMINER ZHENG, LI	
			ART UNIT 1638	PAPER NUMBER
			MAIL DATE 12/03/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/561,720	<b>Applicant(s)</b> ALLISON, RICHARD F.	
	<b>Examiner</b> LI ZHENG	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on August 29, 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 236-306 is/are pending in the application.
- 4a) Of the above claim(s) 242, 259 and 275-306 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 236-241, 243-258 and 260-274 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 236-306 are pending.
2. Applicant's amendments to the specification and submission of new Sequence Listing filed on August 29, 2008 are acknowledged.

Claims 242, 259 and 275-306 are withdrawn for being drawn to non-elected inventions.

Claims 236-241, 243-258 and 260-274 are examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The rejections and objections that are not recited in this Office Action are considered as being withdrawn.

### ***Claim Rejections - 35 USC § 112***

#### ***Scope of Enablement***

6. Claims 236-241, 243-258 and 260-274 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a heterologous polypeptide in plant comprising a) providing a transgenic plant comprising a DNA molecule containing a promoter operably linked to a DNA sequence containing a

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sequence complementary to a coding sequence for a heterologous polypeptide, a sequence complementary to an IRES from a plant virus and a 3' UTR of a first positive strand single-stranded RNA virus; b) growing the transgenic plant ; and c) stimulating synthesis of an RNA complementary to an RNA transcript of the recombinant DNA by infecting the transgenic plant with a second positive strand single-stranded RNA virus closely related to the first one, does not reasonably provide enablement for a method for producing heterologous polypeptide in any cell or any IRES from any source or any stimulus for synthesis of an RNA complementary to an RNA transcript of the recombinant DNA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims, for the reasons of record stated in the Office action mailed April 29, 2008. Applicants traverse in the paper filed August 29, 2008. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that no reference is provided in Gleba or in the Office action to support the conclusion that elements isolated from animal do not support translation in plant cells (response, the paragraph bridging pages22-23).

The Office contends that Gleba reference itself is qualified as a reference to support Office's position. In addition, Dorokhov et al. provided by Applicants could serve as an supporting evidence to show that there are kingdom-specific limitations of viral IRES activity and none of the animal virus IRES elements seem to be active in yeast cell (page 5301, 1<sup>st</sup> paragraph of introduction). Although EMCV IRES is

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moderately active in plant cell, it seems to be an isolated case and the claim is not so limited to a method practiced in plant cell.

Applicants argue that at time of invention, a person skilled in the art would be able to employ routine assays to determine whether a particular IRES sequence could be used in instant invention (response, page 23, 3<sup>rd</sup> paragraph and the paragraph bridging pages 23-24).

The Office contends that the specification fails to reduce the invention to practice. The only working example is only to demonstrate that the replication complex of BMV could recognize and synthesize a complementary copy of a CCMV transgene that contains a complete 3' UTR. The working example does not use IRES to drive the translation of the heterologous gene. Without any working example and given the unpredictability of the art as shown by Gleba et al. and Teycheney et al., in contrast to Applicants' conclusion, undue experimentation would have been required for a person skilled in the art to practice the invention in organisms other than plants, or to select any pairs of the first and second single-stranded RNA viruses, or to use any IRES elements from any sources.

### ***Summary***

No claim is allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Elizabeth F. McElwain/  
Primary Examiner, Art Unit 1638